

REMARKS

Upon entry of the present amendment, claims 1, 3-5, 30 and 32 are pending in the application. Claims 4, 5, and 32 have been amended. Claims 31 and 33 have been cancelled without prejudice or disclaimer. The present amendments are fully supported by the specification and the claims as originally filed. For example, support for the amendments to claims 4 and 5 is found at least at page 2, lines 20-32; at page 7, lines 18-32; and in Figures 1A-1B. Support for the amendment to claim 32 is found at least as page 12, lines 16-24. Accordingly, no new matter has been added by this filing.

Objections to the Specification

The Examiner has objected to the specification for failing to include an updated priority statement.

The "Related Applications" section of the instant application has been amended to indicate that U.S. Application No. 09/618,304 is now issued as U.S. Patent No. 6,777,537, and U.S. Application No. 08/605,378 is now abandoned. Accordingly, withdrawal of this objection is requested.

Claim Objections

The Examiner has objected to claim 4 under 37 C.F.R. § 1.75(c) as being of improper dependent form.

Claim 4, as amended, has been rewritten as an independent claim. Accordingly, Applicants submit that this objection has been obviated and should be withdrawn.

Claim Rejections Under 35 U.S.C. § 101

Claims 32 and 33 have been rejected under 35 U.S.C. § 101 as being directed to non-statutory subject-matter. According to the Examiner, claims 32 and 33 "do not sufficiently distinguish over cells that exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and naturally occurring products." (Office Action, page 3).

Claim 32 has been amended, and claim 33 has been cancelled, thereby rendering all rejections of this claim moot. As amended, claim 32 is directed to an isolated cell comprising a vector that includes a claimed polynucleotide that contains the nucleotide sequence of SEQ ID NO:1, wherein the cell is transformed with the vector. Thus, the cells recited by amended claim 32 are distinguished from naturally occurring cells. As such, this rejection should be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Enablement

Claims 5 and 31-33 have been rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. According to the Examiner, the specification, “while being enabling for a polynucleotide comprising SEQ ID NO:1 or its complement, and an isolated or cultured cell comprising said polynucleotide, does not reasonably provide enablement for (1) a nucleotide sequence comprising nucleotide sequences which hybridize under conditions of medium or high stringency to SEQ ID NO:1 or its complementary sequence; or (2) a non-isolated host cell comprising the claimed polynucleotides.

Claim 5, as amended, recites an isolated polynucleotide encoding a polypeptide which is an osteoclast proton pump subunit, wherein the polynucleotide consists of the nucleotide sequence of SEQ ID NO:1. As described above, amended claim 32 is directed to an isolated cell comprising a vector that includes a claimed polynucleotide, wherein the cell is transformed with the vector. Claim 33 has been cancelled, and all rejections of this claim have been obviated.

Thus, the pending claims, as amended, do not recite nucleotide sequences which hybridize under conditions of medium or high stringency to SEQ ID NO:1, nor do the amended claims recite non-isolated cells comprising the claimed polynucleotides. Accordingly, withdrawal of this rejection is requested.

Written Description

Claims 5, 31 and 33 have also been rejected under 35 U.S.C. § 112, first paragraph for lack of written description. In particular, the Examiner has indicated that “the genus of polynucleotides encompassed by claim 5 is highly variant because a significant number of structural differences between genus members are permitted.” (Office Action, page 10).

Claims 31 and 33 have been cancelled, thereby rendering this rejection moot. Moreover, claim 5 has been amended. As described above, independent claim 5 has been amended to recite an isolated polynucleotide encoding a polypeptide which is an osteoclast proton pump subunit, wherein the polynucleotide consists of the nucleotide sequence of SEQ ID NO:1. The claimed polynucleotide is described throughout the specification, *e.g.*, at least at page 2, lines 20-32; at page 7, lines 18-32; and in Figures 1A-1B. Accordingly, Applicants submit that amended claim 5 is fully described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. As such, this rejection should be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 5, 31 and 33 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. According to the Examiner, the terms “medium stringency” and “high stringency” in claim 5 are “relative terms which render the claim indefinite.” (Office Action, page 12).

As noted above, amended claim 5 does not recite nucleotide sequences which hybridize under conditions of medium or high stringency to SEQ ID NO:1. Accordingly, Applicants believe that this rejection has been obviated and should be withdrawn.

Claim Rejections Under 35 U.S.C. § 102

The Li 1996 Reference

Claims 1, 3-5, and 30-33 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Li *et al.*, Biochemical and Biophysical Research Communications, vol. 218: 813-821 (Jan. 26, 1996) (“the Li 1996 reference”). The Examiner has stated that the Li 1996 reference “although sharing two inventors with the instant application, is considered to be invented by others because it has an author that is not include in the application.

Applicants respectfully traverse this rejection. The Li 1996 reference does not describe an invention that was known or used by others before invention by Applicants under 35 U.S.C. § 102(a). The instant application is based in part on work that was reported in a manuscript that subsequently published as the Li 1996 reference that the Examiner has cited against this

application. Dr. Philip Stashenko, one of the named inventors of the instant application and an author of the Li 1996 reference, was the Principal Investigator of the laboratory where the inventions described in the instant Application were invented. While Wei Chen was an author of the Li 1996 reference, Dr. Chen is not an inventor of the subject matter of the claimed invention. Applicant notes that the criteria for determining the authorship of a scientific publication, such as a journal article, are not identical to the criteria for determining inventorship in a patent application. Thus, the fact that a scientific publication names more authors than the inventors listed on a given application does not mean that the publication is “by another”.

Moreover, the inventions claimed in the instant application were invented before the publication date of the Li 1996 reference. The work presented in Figure 2 on page 816 and the description at pages 814-815 of the Li 1996 reference corresponds to the description at pages 6-8 and Figures 1A-1B of the as-filed application. The Materials and Methods on pages 813-814 of the Li 1996 reference corresponds to the Examples provided on pages 14-16 of the specification. The description provided at pages 815 and 819-820 corresponds to the description at pages 8-9 of the as-filed specification.

Thus, the polynucleotides described in the Li 1996 reference are the same as the polynucleotides described and claimed in this Application. Accordingly, the inventions claimed in this Application were necessarily invented before the publication date of the Li 1996 reference. The polynucleotides recited by the amended claims, were not, therefore, known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before we invented the claimed inventions. As such, the Li 1996 reference is not prior art under 35 U.S.C. § 102(a), and this rejection should be withdrawn.

The Li 1995 Reference

Claims 32 and 33 have also been rejected under 35 U.S.C. § 102(a) as being anticipated by Li *et al.*, J. Bone Mineral Res., vol. 10(8): 1197-1202 (Aug. 1995). According to the Examiner, “the instant specification teaches that a polynucleotide comprising SEQ ID NO:1 can be isolated from cells found in osteoclastoma tumor ... these cells inherently comprise a polynucleotide comprising SEQ ID NO:1.” (Office Action, page 14).

Claim 33 has been cancelled, thereby rendering this rejection moot. Moreover, claim 32 has been amended to recite an isolated cell comprising a vector that includes a claimed polynucleotide, wherein the cell is transformed with the vector. The Li 1995 reference, however,

does not disclose or suggest isolated cells that are transformed with a vector that contains the nucleotide sequence of SEQ ID NO:1. Accordingly, amended claim 32 is novel over this reference, and this rejection should be withdrawn.

Peng

Claims 5, 31 and 33 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Peng *et al.*, J. Biol. Chem., vol. 269(25):17262-17266 (1994) (“Peng”). In particular, the Examiner has indicated that “the nucleic acid sequence taught by Peng comprises a sequence that would hybridize with the complement of SEQ ID NO:1 under conditions of high stringency.” (Office Action, page 15).

As described above, claim 5, as amended, does not recite nucleotide sequences which hybridize under conditions of medium or high stringency to SEQ ID NO:1. Rather, amended claim 5 is directed to an isolated polynucleotide encoding a polypeptide which is an osteoclast proton pump subunit, wherein the polynucleotide consists of the nucleotide sequence of SEQ ID NO:1. Moreover, claims 31 and 33 have been cancelled, thereby obviating all rejections of these claims.

Peng, however, does not describe or suggest a polynucleotide that consists of the nucleotide sequence of SEQ ID NO:1. Thus, this reference fails to teach every element of the claimed invention. As such, amended claim 5 is novel over the Peng reference. Withdrawal of this rejection is, therefore, requested.

Stashenko

Claims 5, 31 and 33 have also been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,552,281 by Stashenko *et al.* (“Stashenko”). According to the Examiner, “SEQ ID NO:25 of Stashenko would hybridize to instant SEQ ID NO:1 under conditions of high stringency.” (Office Action, page 16).

As described above, claims 31 and 33 have been cancelled, thereby obviating all rejections of these claims. In addition, Applicants note that amended claim 5 does not recite nucleotide sequences which hybridize under conditions of medium or high stringency to SEQ ID NO:1. As amended, claim 5 recites an isolated polynucleotide encoding a polypeptide which is an osteoclast proton pump subunit, wherein the polynucleotide consists of the nucleotide sequence of SEQ ID NO:1.

Stashenko, however, fails to teach or suggest any polynucleotide that includes the nucleotide sequence of SEQ ID NO:1, let alone a polynucleotide that consists of SEQ ID NO:1. Thus, amended claim 5 is novel over the Stashenko reference. As such, the Examiner should withdraw this rejection.

Double Patenting Rejections

Non-Statutory Double Patenting Rejections

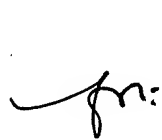
Claims 5, 31 and 33 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 4 of U.S. Patent No. 6,403,304 (“the ‘304 patent”). According to the Examiner, “SEQ ID NO:25 of the ‘304 patent is 100% identical to the complement to residues 2472-2632 of instant SEQ ID NO:1”, and, therefore, “SEQ ID NO:25 of the ‘304 patent would hybridize to instant SEQ ID NO:1 under conditions of high stringency.” (Office Action, page 17).

As described above, the pending claims have been amended and no longer recite nucleotide sequences which hybridize under conditions of medium or high stringency to SEQ ID NO:1. In particular, claim 5, as amended, is directed to an isolated polynucleotide consisting of the nucleotide of SEQ ID NO:1. However, the ‘304 patent does not disclose or suggest such a polynucleotide. Accordingly, Applicants submit that the polynucleotide recited by amended claim 5 is not obvious in view of the claims of the ‘304 patent. As such, the amended claims are patentably distinct from the claims of the cited reference, and Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Applicants submit that the application is in condition for allowance and such action is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact any of the undersigned at the telephone number provided below. The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 25669-012
CON DIV.

Respectfully submitted,

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